



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Clinical Research (OCR), Office of the Director (OD), National Institutes of Health, will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Anne Zajicek, M.D., Pharm.D., Deputy Director, Office of Clinical Research, NIH Office of the Director, Building 1, Room 208A, MSC-0155, Bethesda, Maryland, 20892 or call non-toll-free number (301) 480-9913 or E-mail your request, including your address to: zajiceka@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance

of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research, 0925-0764, exp., date 11/30/2022, Office of Clinical Research (OCR), National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: The purpose of this survey is to assess the long-term impact and outcomes of clinical research training programs provided by the OCR located in the NIH OD over a ten-year follow-up period. The information received from respondents will provide insight on the following: impact of the courses on (a) promotion of professional competence, (b) research productivity and independence, and (c) future career development within clinical, translational and academic research settings. These surveys will provide preliminary data and guidance in 1) developing recommendations for collecting outcomes to assess the effectiveness of the training courses, and 2) tracking the impact of the curriculum on participants' ability to perform successfully in academic, non-academic, research, and non-research settings.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,674.

Estimated Annualized Burden Hours

Form Name	Type of Respondents	Estimated Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
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OCR Learning Portal Registration	Healthcare Professionals	2000	1	10/60	333
	Students	3000	1	10/60	500
	General Public	1000	1	10/60	167
Introduction to the Principles and Practice of Clinical Research (IPPCR) Lecture Evaluation	Healthcare Professionals	1000	1	10/60	167
	Students	2000	1	10/60	333
	General Public	1000	1	10/60	167
IPPCR Final Course Evaluation	Healthcare Professionals	1000	1	10/60	167
	Students	2000	1	10/60	333
	General Public	1000	1	10/60	167
Principles of Clinical Pharmacology (PCP) Lecture Evaluation	Healthcare Professionals	1000	1	10/60	167
	Students	2000	1	10/60	333
	General Public	1000	1	10/60	167
PCP Final Course Evaluation	Healthcare Professionals	1000	1	10/60	167
	Students	2000	1	10/60	333
	General Public	1000	1	10/60	167
NIH Summer Course in Clinical and Translational Research Course Evaluation	Healthcare Professionals	20	1	10/60	3
Sabbatical in Clinical Research Management Course Evaluation	Healthcare Professionals	20	1	10/60	3
	Total	22,040	22,040	3,674

Dated: August 22, 2022.

Tara A. Schwetz,

Acting Principal Deputy Director,

National Institutes of Health.

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